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Robert T. Hrubiec, Ph.D, J.D.
Cephalon, Inc.
41 Moores Road
P.O. Box 4011
Frazer, PA 19300

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,927,855

Dear Dr. Hrubiec :

An order granting interim extension under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 4,927,855 for a period of 335 days. This third interim extension under 35 U.S.C. § 156(e)(2) is for less than one year since Applicant, in accordance with their application for patent term extension under 35 U.S.C. § 156(d)(1), is entitled to no more than 1,066 days extension from the original expiration date of U.S. Patent No. 4,927,855.

While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website: <http://www.fda.gov/opacom/morechoices/fdaforms/default.html> (<http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf>).

Inquiries regarding this communication should be directed to the undersigned by telephone at (571) 272-7755, or by e-mail at mary.till@uspto.gov.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

RE: NUVIGIL™ (armodafinil)
Docket No.:

Attention: Beverly Friedman

UNITED STATES PATENT AND TRADEMARK OFFICE


In re Cephalon Inc. :
Request for Interim Patent Term Extension : **ORDER GRANTING**
U.S. Patent No. 4,927,855 : **INTERIM EXTENSION**

Cephalon, Inc., the owner of record in the United States Patent and Trademark Office of U.S. Patent No. 4,927,855, filed a third application under 35 U.S.C. § 156(e)(2) for interim extension of U.S. Patent No. 4,927,855 on April 3, 2009. The previously extended term of the patent is due to expire on May 22, 2009. The patent claims the active ingredient armodafinil in the human drug product NUVIGIL® and a method of use of said product which was approved by the Food and Drug Administration for commercial marketing or use on June 15, 2007. An extension of 1,066 days from the original expiration date was requested in an application for patent term extension under 35 U.S.C. § 156 filed on July 27, 2007.

The initial USPTO review of the application indicates that the subject patent is eligible for an extension of the patent term under 35 U.S.C. § 156. Because the extended term of the patent will expire on May 22, 2009, before a certificate of extension can be issued, further interim extension of the patent term under 35 U.S.C. § 156(e)(2) is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,927,855, is granted for an additional period of 335 days to further extend the patent from the extended expiration date of May 22, 2009, until the extended expiration date, April 22, 2010.

04/15/09
Date



John J. Doll
Acting Under Secretary of Commerce for Intellectual Property and
Acting Director of the United States Patent and Trademark Office